Exhibit 5

EXPERT REPORT

Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

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Cardinal Health failures came not necessarily in the design of its KYC system but in the **operation** of the system. Due diligence files should be complete, accurate, and maintained on each customer to allow a registrant to have a sufficient understanding of each specific customer. These customer files also must be accessible to allow a registrant to use this information when it receives an order that it believes is potentially suspicious. Based on the information that I have reviewed Cardinal did not maintain sufficient KYC/due diligence files on each of its customers to establish sufficient knowledge of the customers.

Cardinal also separated its retail customers into two categories: (a) retail independents (RI) and (b) retail chains. During Policy Period #2 Cardinal treated retail chain customers different from retail independents as it relates to KYC/due diligence. Cardinal Health relied on chain customers to conduct their own due diligence and investigations related to potential suspicious orders and diversion concerns.[224] This practice continued even after Cardinal Health was told by the DEA in November 2009 that Cardinal Health "must exercise the same level of oversight with respect to retail chain pharmacies and retail independent pharmacies."[225] The CSA does not permit a registrant to delegate or shift the burden of maintaining effective controls to a third party, even if that third party is also a registrant. These practices were not sufficient for Cardinal Health to meet its obligations under the security requirement.

c. Policy Period #3 (2012 to Present):

Cardinal Health's third redesign of its SOM program (2012-present) occurred after the second enforcement action by the DEA. Cardinal Health asserted that this system was less subjective but in reality it was the contrary. The system that Cardinal implemented in 2013 continued to utilize both the threshold system and the KYC/due diligence component. However, Cardinal Health's revised system now based the thresholds solely on the individual customer's information without consideration for the population that it served or comparison to similar customers.[226] This was violative of Cardinal Health's own Standard Operating Procedures (SOP).[227]

Cardinal also developed working guidelines, or "General Work Instructions," that, according to Todd Cameron, are utilized more frequently by Cardinal and contain more "action oriented detail" than the Standard Operating Procedures.[228] One set of these guidelines describe a process for Cardinal to permit customers who have exceeded their threshold for a particular drug to receive a certain percentage of dosage units over the threshold once per accrual period per drug

[224] *See* Declaration of Michael A. Moné, CAH_MDL_PRIORPROD_DEA12_00014053 at page 13; CAH_MDL2804_03262274, 03262438.

[225] *See* Correcting Declaration of Michael A. Moné, CAH_MDL_PRIORPROD_DEA12_00013747 at page 4; Depo. of Steven Morse, 113:8-13; Depo. of Christopher Forst, 33:9-34:5.

[226] *See* Depo. of Todd Cameron, 54-69.

[227] CAH_MDL_PRIORPROD_AG_0028694.

[228] *See* Depo. of Todd Cameron, 118:2-119:5.

family.[229] The amount a customer is allowed to receive above its threshold depends on the current threshold limit for that customer for the particular drug – 15% over if the threshold is between 0-9,999, 10% if between 10,000-19,999, or 5% if 20,000 or more.[230]

According to internal documents produced by Cardinal, it appears that Cardinal did not want its use of a "percentage over threshold" process to be disclosed to the DEA. In April 2014, Cardinal's Director of Investigations QRA, Ullrich Mayeski, tasked Cardinal employees Kim Hownestein and Kimberly Anna-Soisson to create a presentation for Mayeski to give to Cardinal Compliance Officers concerning how the Compliance Officers would "facilitate an overview conversation about the SOM program during a DEA Cyclic Inspection."[231] Ullrich also advised Howenstein and Anna-Soisson that the presentation would be shared with the DEA during an on-site inspection.[232] Howenstein and Anna-Soisson developed a draft and in an email on May 1, 2014 discussing the document, Anna-Soisson stated that she "intentionally left out the part about releasing beyond the [threshold]" because she "did not want to draw attention to the practice but agree that the CO's should know it exists."[233] In an instant message exchange, Anna-Soisson then told Mayeski that she "did not want to draw attention to what I believe they would consider questionable at best so we agreed and put it in the notes only section. That way CO's know it occurs but it isn't so obvious."[234]Anna-Soisson had previously raised the issues with this practice in an email to Todd Cameron and Christopher Forst, pointing out that analysts were permitted to release a percentage over threshold even in instances where a threshold increase was not warranted or where the customer was "failing."[235]

This is the first timeframe for which Cardinal Health has produced specific suspicious orders related to CT1 jurisdictions. Cardinal Health identified 147 suspicious orders for Summit and Cuyahoga Counties combined from 1/1/13 to present.[236] Cardinal Health's system was designed so that if a customer exceeded a threshold and had a suspicious order reported based on that breach Cardinal Health was not to ship any more of that base code/drug family to that customer until the threshold reset at the end of the monthly cycle or there was adequate due diligence done to clear the order and subsequent orders. [237] I was able to compare Cardinal's distribution data to the suspicious orders reported after 1/1/2013.[238] Additionally, I conducted a further review to

[229] CAH_MDL2804_00012244, 00012249-00012267.

[230] *Id*. at CAH_MDL2804_00012263-00012264.

[231] CAH_MDL2804_00012244.

[232] *Id*.

[233] CAH_MDL2804_00012953.

[234] CAH_MDL2804_02350970.

[235] CAH_MDL2804_00009412, 00009413.

[236] CAH_MDL2804_00000013.

[237] *See Deposition of Shirlene Justus*, July 13, 2018 at 86:14 to 88:6.

[238] CAH_MDL2804_00000012; CAH_MDL2804_00000014.

determine for which orders there was any[239] due diligence investigation (or review) conducted and documented prior to shipping any further products of this same drug family. Cardinal had repeatedly failed to conduct and document adequate due diligence to dispel the suspicious activity prior to shipping additional opioids of the same drug family. The chart contained in Schedule III shows that Cardinal Health continued to ship the same opioid drugs to customers who Cardinal Health had already determined were placing suspicious orders in CT1 46% of the time (68 orders), and of those orders, 92% (63 orders) were shipped with no documented due diligence

3. Cardinal Health failed to *report* suspicious orders of controlled substances in violation of the *reporting requirement* set forth in 21 C.F.R. § 1301.74(b).

Cardinal Health timely reported zero suspicious orders in CT1 jurisdictions (Summit and Cuyahoga Counties, Ohio) from 1996 to at least 2008, based on the records provided. The ILR is an after-the-fact distribution report which is insufficient. Cardinal has not been able to produce suspicious orders that were reported to the DEA for CT1 during Policy Period #2 (2008-2012). However, it was Cardinal Health's practice not to report suspicious orders but to "report an order as suspicious when the customer appeared suspicious" and Cardinal Health was going to terminate service to that customer.[240] Waiting to the point of termination of a customer prior to reporting any suspicious orders related to the customer is not sufficient to meet the reporting requirement. This conclusion is supported by several documents produced by Cardinal Health. First, Cardinal's November 1, 2012 Audit Committee Meeting packet indicates that during fiscal years 2010 and 2011 Cardinal only reported 30 and 47 suspicious orders, respectively, nationwide. This is in stark contrast to the 6,326% increase of reported suspicious orders that allegedly occurred in 2012, according to the document.[241] Additionally, during this same period of time the Baltimore DEA office provided a presentation to Cardinal Health that, among other things, outlined that between 2008 and October 1, 2011, Cardinal did not report any suspicious orders of oxycodone products in Maryland.[242]

Finally, during Policy Period #3 Cardinal Health reported 147 suspicious order but continued to ship the same base codes to many of those customers.[243] Any additional orders from these customers without having been cleared would also constitute a suspicious order and should have been reported to the DEA as such. Also during the 2012-2015 timeframe, Cardinal's employee testified that Cardinal failed to report to the DEA approximately 14,000 separate suspicious orders from around the country. According to Mr. Cameron these were for "subbase

[239] Whether the due diligence was sufficient or not is an additional consideration.

[240] *See Investigation Report of the Special Demand Committee*, CAH_MDL_PRIORPROD_HOUSE_0003331 at page 36; *also see Supplemental Declaration of Michael A. Mone*, CAH_MDL_PRIORPROD_DEA12_00014762 at page 8; *also see* CAH_MDL2804_3262274, 03262438.

[241] CAH_MDL2804_03262274, 03262438.

[242] CAH_MDL2804_02509732, 02509741.

[243] *See* "Know Your Customer" section above.